

REMARKS

I. Introduction

Applicants respectfully request reconsideration of the present application in view of the accompanying Rule 132 declaration, the foregoing amendments, and this commentary.

II. Status of the Claims and Summary of Amendments Thereto

Applicants gratefully acknowledge the PTO's indication that claims 24-27 are allowed. Claims 18-22 were cancelled previously, and claims 2, 4, 5 and 13 are presently cancelled. Claim 1 is amended to recite pharmaceutical compositions. Claims 6-12 are amended to prescribe more clearly that compounds are claimed. Claims 14-17 are revised to depend from such compound claims, while newly presented claim 28 depends from composition claim 1. Finally, claim 23 as revised omits the compound designated as "65B."

Upon entry of these changes, claims 1, 3, 6-12, 14-17, and 23-28 will be pending.

III. The Office Action

In the non-final Office Action, the PTO has maintained previous grounds for rejection and presented a new ground for rejection. Applicants highlight here why the present amendments, considered in light of the accompanying Rule 132 declaration, should not be rejected for the reasons identified in the Office Action.

A. Objection to the Claims

The PTO again objected to claims 3 and 6-12, otherwise allowable, for allegedly depending from a rejected base claim. Office Action at page 4. Applicants' previous response pointed out correctly that none of these claims is in dependent form, obviating the PTO's stated reason for objection. Accordingly, they urge that the PTO withdraw this objection and acknowledge allowability of these claims.

B. Rejection of Claims Under 35 U.S.C. § 102(b)

The PTO maintained its rejection of claims 1, 2, 4, 5, 13-17, and 23 for alleged anticipation by U.S. Patent Application Publication No. 2002/0193423 to Northcote *et al.* (“Northcote”) and L. W. West *et al.*, *J. Org. Chem.* **2000**, 65: 445-49 (“West”). Office Action at page 2. In doing so, the PTO discredited Applicants’ previous argument that Northcote and West teach inactive enantiomers and, hence, fail to teach or suggest the claimed compounds of specified stereochemistry. *Id.* The PTO also stated that a skilled artisan would have recognized from Northcote or West that “the compound” (presumably “peloruside A” as shown in the references) would have anti-proliferative activity.

The rejection is moot as to cancelled claims 2, 4, 5, and 13. To the extent that the rejection might apply to the claims as amended, Applicants respectfully traverse the rejection.

In a recent telephone discussion of this rejection with the undersigned, the Examiner was heard to indicate her willingness to consider further evidence concerning what the cited publications actually teach. To this end, the accompanying declaration (“the De Brabander declaration”) attests to the fact that the cited prior art discloses an *inactive* “peloruside A,” incorrectly identified, with no predictive commentary or guidance for the skilled artisan.

More specifically, the declarant highlights how West and Northcote depict a molecule that is identified as “peloruside A” but that is actually an inactive stereoisomer of peloruside A. *See*, for example, paragraph 7 of the De Brabander declaration. Informed by these publications, therefore, a person of ordinary skill would have failed in attempting to prepare a pharmaceutical composition of “peloruside A,” per Northcote. Moreover, Northcote implicates no principle or guidance by which the skilled artisan, confronted with this failure, could somehow have progressed to a pharmaceutical composition.

It necessarily follows that neither cited publication would have placed into the hands of the relevant public a pharmaceutical composition as presently claimed. Accordingly, Northcote or West do not anticipate claim 1.

The foregoing considerations also underscore why Northcote and West do not validate the rejection of the remaining claims. For instance, the publications do not teach any of the methods claimed in claims 14-17 because the present claims recite no compounds disclosed by Northcote or West. Also, compound claim 23 does not encompass peloruside A. Finally, method claims 28-31 require the use of the pharmaceutical composition of claim 1 which, as demonstrated above, is neither taught nor suggested by the cited publications. Thus, Applicants respectfully urge the PTO to reconsider with withdraw this ground for rejection.

C. Rejection of Claims Under 35 U.S.C. § 103(a)

The PTO rejected claims 1, 2, 4, 5, 13-17, and 23 for alleged obviousness over the combination of West and Northcote. On page 3 of the Office Action, the PTO set out essentially the same concerns advanced under the section 102 rubric, already considered above. Additionally, the PTO stated that peloruside A derivatives bearing alkoxy and acyloxy groups are “commonly known” to have similar pharmaceutical properties as those of peloruside A itself. As a result, according to the PTO, a person of ordinary skill in the art would have been motivated to make the various derivatives pursuant to Northcote and West.

The rejection is moot as to cancelled claims 2, 4, 5, and 13. Because neither reference supports the rejection insofar as it might pertain to the other claims as amended, Applicants respectfully traverse.

The De Brabander declaration emphasizes that Northcote and West each depict a compound, “peloruside A,” that is inactive. Neither publication advances any principle or *a priori* expectation of success by which a person of ordinary skill in the art might have formulated a pharmaceutical composition as presently claimed. Thus, the skilled artisan, confronted with the inactivity of the disclosed “peloruside A,” could have had no expectation whatsoever that the alkoxy and acyl derivatives mentioned by the PTO would possess biological activity. Based on Northcote and West, moreover, the person of ordinary skill would not have known how to make an active (hence, “pharmaceutical”) formulation, much less how to practice the methodology of claims 14-17 and 28.

To the contrary, the cited combination of publications would have left the person of ordinary skill with no recourse other than empirical experimentation in attempting to identify an active compound, its formulation, and its use in the claimed methods, respectively. Such unguided experimentation, even if ultimately successful, does not manifest the requisite motivation and expectation of success that is required for a *prima facie* case of obviousness. MPEP § 2143. The present claims are patentable over Northcote and West, therefore, and this ground for rejection should be withdrawn.

IV. Conclusion

Applicants believe that the present application is now in condition for allowance. To that end, Applicants respectfully request favorable reconsideration of the application as amended. Should Examiner Owens believe that further discussion is necessary, she is kindly invited contact the undersigned by telephone.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.